REMARKS

Applicants have carefully considered the Examiner's comments set forth in the Office Action of January 21, 2010 and respectfully request reconsideration of the above-identified application in view of the following remarks.

Claims 1 to 61 remain in this application. Claims 1-21, 23, 25, 26, 32-46, 50, and 54 are withdrawn. Claims 29 and 30 are amended solely in the interest of clarity, as supported by, for example, the original language of these claims. No new matter has been added.

The Office Action

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

Claims 29 and 30 were rejected for lacking antecedent basis in the claims from which these claims depend. Claim 29 has been amended to depend from claim 28 rather than claim 22 and claim 30 has been amended to replace the term "immune cell" with the term "antigen presenting cell", thus obviating the rejection.

Claim Rejections – 35 U.S.C. § 103

Claims 22, 24, 27-31, 47-49, 51-53, and 55-61 were rejected for being obvious having regard to Qian et al. (U.S. 2004/0043483) in view of Li et al. (Journal of Immunology, 2001, 166:5619-5628) and Tuschl et al. (WO 02/44321). We disagree with the Examiner. Each of the independent claims is a method of treating specific immune disorders or transplant rejection in a patient by administering an siRNA that alters or suppresses T cell activity. This is not taught or suggested by the cited references, alone or in combination.

Qian et al. is not relevant to the presently claimed invention. This reference is directed to the use of antisense technology, amongst other things, to reduce transplant rejection or for treating an autoimmune disorder. Antisense technology is not the same as siRNA technology. Antisense technology uses a single-stranded RNA sequence that binds to an mRNA sequence of interest in order to reduce its expression. The single-stranded RNA antisense molecule binds to the mRNA sequence of interest and simply blocks translation physically. In contrast, siRNA uses short double-stranded pieces of RNA. siRNAs do not work in the same way as antisense RNAs.

siRNAs work by targeting the RNA-induced silencing complex to bind to and degrade the mRNA. siRNA technology is much more efficient and effective than antisense technology. Importantly, Qian et al. do not teach or suggest the use of siRNA technology, as is presently claimed, let alone for suppressing T cell activity and thereby treating autoimmune disorders or inhibiting transplant rejection.

Li et al. is also not relevant to the presently claimed invention. This reference is directed to the use of an antibody that binds to and antagonizes IL-12 translated protein. Using antibodies is a completely different technology to that of siRNA, since siRNA inhibits expression of a gene at the level of the mRNA, whereas antibodies simply inhibit the function or binding of a fully formed protein. siRNA inhibition of mRNA translation is very different from inhibition of a fully formed and processed protein through antibody binding. Like Qian et al., Li et al. fails to teach or suggest the use of siRNA technology, as is presently claimed.

Tuschl et al. is directed to RNA interference technology in general and does not teach or suggest targeting the presently claimed endogenous genes or treating the presently claimed conditions or disorders. For example, independent claim 22 is directed to the treatment of an immune disorder characterized by inappropriate T cell activity in a subject. The claimed method comprises administering an siRNA that targets IL-12 and/or IFN-gamma for a time and amount sufficient to alter T-cell activity and treat the disorder. Tuschl et al. fails to teach or suggest the use of an siRNA to target IL-12 and/or IFN-gamma, let alone for a time and amount sufficient to alter T cell activity and thereby treat the disorder, as is presently claimed. Similarly, independent claim is directed to decreasing the immunogenicity and rejection potential of an organ for transplantation. The claimed method comprises perfusing the organ with a composition that suppresses T cell activity and comprises at least one siRNA that inhibits the expression of an endogenous target gene encoding a surface marker, a chemokine, a cytokine, an enzyme, or a transcriptional factor produced within an antigen producing cell. Tuschl et al. fails to teach or suggest the use of an siRNA to target the recited endogenous target genes, let alone in a composition that suppresses T cell activity for the decreasing the immunogenicity and rejection potential of an organ for transplantation. The remaining independent claims are similar and, like claims 22 and 47, Tuschl et al. fails to teach or suggest each and every feature recited therein.

Thus, it is clear from the above that, while each of the cited references may generally discuss one method of improving transplant rejection or one method of blocking IL-12, none of

the cited references, alone or in combination, teaches, suggests, or enables using siRNA in order to suppress or alter T cell activity, as is presently claimed. The claimed methods specifically and stably knock-out one or more endogenous genes of interest thereby suppressing immune function. This is important and advantageous in many disorders and conditions. These claimed novel and unobvious treatments were not contemplated prior to the presently invention and it required the ingenuity of a skilled person in order to arrive at the claimed methods. For at least these reasons, we request that the rejection be withdrawn.

CONCLUSION

For the reasons detailed above, it is submitted all remaining claims (Claims 1-61) are now in condition for allowance. An early notice to that effect is therefore earnestly solicited.

☒ This is an authorization under 37 CFR 1.136(a)(3) to treat any concurrent or future reply, requiring a petition for extension of time, as incorporating a petition for the appropriate extension of time.

☒ The Commissioner is hereby authorized to charge any filing or prosecution fees which may be required, under 37 CFR 1.16, 1.17, and 1.21 (but not 1.18), or to credit any overpayment, to Deposit Account 192253.

In the event the Examiner considers personal contact advantageous to the disposition of this case, he/she is hereby authorized to call Dr. Lola A. Bartoszewicz, at Telephone Number (416) 849-8420.

Respectfully submitted,

SIM & MCBURNEY

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Date

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